The benefits and bureaucracy of the ethics process

KT-EQUAL Coventry
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Outline of presentation

1. Definitions
2. The purpose of research
3. Some reasons for the increased interest in ethical issues
4. The main ethical principles and benefits in research
5. Some differences between types of research
Outline of presentation (ctd)

6. Types of scrutiny in the UK
7. Specific issues to do with research with users
8. How to ensure an ethical approach in research
9. Is the process too bureaucratic?
10. Guidelines
11. Conclusion
1. Some definitions of ethics

• ‘Science of morals’ ‘Moral principles or code’
  Oxford dictionary
• ‘Relating to, or treating of, morals’ ‘Rules of conduct’
  Collins dictionary
Is there common agreement about ethical principles

Are there variations according to culture, time and place
2. The purpose of research

- Advance knowledge
- Produce future benefits
- Check current practice
3. Some reasons for the increased interest in ethical issues

- Problems and scandals
- Greater awareness of rights
- A more litigious society
- Greater involvement of service users
- Concern by funders (especially Research Councils)
3. Some reasons for the increased interest in ethical issues (ctd)

- Concern about social care and the social sciences
- Proliferation of small research
- An increase in sales and marketing disguised as research
- Falling response rates
Factors associated with drop out from longitudinal studies

These include:

- Being older
- Having chronic ill health
- Being cognitively impaired
- Coming from a lower socio economic group
- Having fewer years in education

These point to older and disabled people being more likely to drop out of studies
4. The main ethical principles in research

- The value of life
- Goodness or rightness
- Justice or fairness
- Truth-telling or honest
- Individual freedom

(Thiroux, 1980)
The 4 generally accepted ethical principles

• Beneficence – do good
• Non-maleficence – do not harm
• Autonomy
• Justice

But different interpretations?
Some overarching principles and issues: Key points

Research is expected to be designed and conducted in a way which meets 6 key ethical principles:

• Research is designed and conducted to ensure integrity and quality
• Research staff and participants are fully informed about the study
• Participants’ privacy is respected and confidentiality of data is protected

(With acknowledgment to Mary Boulton 10.1.06 Training session at KCL)
Key points (ctd)

- Participants to take part voluntarily
- Harm to participants is avoided
- Research and researchers are independent, or conflict of interests are declared

Also that research should be subject to proper ethical scrutiny by organisations and monitored over the course of the research
General principles

• Consent (useful guidance: www.doh.gov.uk/consent)
• Confidentiality
• Conduct

(the 3 Cs – from a previous set of guidelines by the Social Research Association)
The benefits of ethical approval

• To get advice on the best ethical practice
• For insurance purposes
• Because in many Universities it is a disciplinary offence to undertake research without ethical approval
• The process is there to protect the researcher as well as the participant
• To obtain funding
• To get publications
5. Some differences between types of research

Different kinds of research:
- Research on patients
- Research on ‘healthy volunteers’/participants
- Research on animals
Types of research on human participants

- Invasive (e.g. taking blood)
- Administration of a product (e.g. alcohol, food)
- Physical activity (e.g. cycling, ct scans)
- Non invasive samples (e.g. saliva, urine)
- Human tissue samples
- Interviews/questionnaires/focus groups/observation (e.g. abortion, smoking, professional practice)
6. Types of scrutiny in the UK

a. National Health Service (NHS) Research Ethics Committees (LRECs)

b. For non medical including the social sciences (University Research Ethics Committees)

c. Others
a. The role of NHS Research Ethics Committees

• ‘The committee convened to provide independent advice to all participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards’

(Central Office for Research Ethics Committees and note that the central office is now called National Research Ethics Service which comes under the National Patient Safety Agency)
The role of NHS Research Ethics Committees

‘Research Ethics Committees are responsible for acting primarily in the interest of potential research participants and concerned communities, but they should also take into account the interests, needs and safety of researchers who are trying to undertake research of good quality. However, the goals of research and researchers, while important, should always be secondary to the dignity, rights, safety and well-being of the research participants’ (DH, July 2001)
Scope of NHS Research Ethics Committees

- Patients and users of the NHS
- Relatives and carers of patients and users
- Organs, fetal material, dead
- Use of, or potential access to, NHS facilities or premises
- NHS staff in a professional capacity
Scope of NHS Research Ethics Committees (ctd)

• Research involving adults who lack capacity to consent

• Research involving human tissue for research conducted on premises that do not have the relevant licence
b. Ethical procedure for non medical research in UK Universities

- A varied picture
- See the report ‘University Research Ethics Committees: their role, remit and conduct’ by Anthea Tinker and Vera Coomber, Nuffield Foundation, 2004.

Available on the web – go to Institute of Gerontology
c. Others

For example:

• Department of Health Committee for Social Care started 2009
7. Specific issues to do with research with users

- There should be no automatic assumption that either group are not able to take part in research.
- Disabled people have been to the forefront in insisting that research involves them at all stages (including what is researched).
- DH* say that ‘It should never be assumed that people are not capable of making their own decisions, simply because of age and frailty’ (p.1).
- The scandal of age bias and lack of research on older people (e.g. over drugs).

* DH (2004) Seeking consent; Working with older people
7. Specific issues to do with research with users

• Note the New Dynamics of Ageing Workshop 19.10.10 which raised issues such as:
  • who should be involved?
  • How much time and remuneration should there be?
  • Older people as researchers
  • PIs who are themselves older
8. How to ensure an ethical approach in research

The need to develop a culture to ensure that ethical issues are of prime importance for policy makers, practitioners and researchers
9. Is the process too bureaucratic?

- The Academy of Medical Sciences thinks so. See their report ‘A new pathway for the regulation and governance of health research’ (January 2011)
- A well written and argues report with sensible suggestions for streamlining procedures.
- However very dismissive of University RECs
The report only deals with health and it focuses on NHS committees. However it says (p.77):

‘University ethics committees operate on an independent basis, with no external oversight or authority, and generally consider issues of an ethical nature arising from teaching or research in their institutions. Because all health research in the NHS is reviewed by RECs, which are centralised to ensure that review is taken to UK wide standards, there is not generally a requirement for a separate university ethics committee review. University ethics committees are therefore not considered further in this report.'
10. Guidelines provided by different professional bodies and funders

For example the British Psychological Society (2010)
11. Conclusion

• An issue that will not go away
• Becoming of even greater importance e.g. insurance, Data Protection Act, Human Rights Act
• Growing attention by the media
• Greater awareness by the public
Suggested reading


Tinker, A and Coomber, V (2004) University Research Ethics Committees: Their role, remit and conduct, Nuffield Foundation/KCL